

## **Chemistry Unit Document Control Procedures**

### **1 Purpose**

These procedures detail the methods used in the Chemistry Unit (CU) to comply with the *FBI Laboratory Quality Assurance Manual* and *FBI Laboratory Practices for Document Control*.

### **2 Scope**

These procedures apply to personnel that prepare and use CU controlled documents. These include Standard Operating Procedures (SOPs), Instrument Operation and Systems Support (IOSS) Protocols, *CU Quality Assurance and Operations Manual* documents, *CU Training Manual* documents, and equipment manuals/externally produced quality documents that CU personnel are required to follow for specific SOPs.

### **3 Document Distribution and Control**

#### **3.1 IOSS Protocols**

CU personnel will also have access to controlled copies of IOSS Protocols on CHEMNET.

#### **3.2 Instrumentation Manuals and Externally Produced Quality Documents**

Instrumentation manuals and other externally produced quality documents (to include electronic versions of these manuals/documents) that CU personnel are required to follow for specific SOPs will be controlled. This will be accomplished by labeling each applicable manual/document as “controlled” on at least the first page or cover of the manual/document or directly on the electronic storage device containing the manual/document. Additionally, a review signature and an approval signature are required, along with the dates of the signatures. For electronic manuals/documents, these signatures and dates are recorded on the *CU Electronic Instrument Manuals Under Document Control Review and Approval Document*, which is stored in the UC’s office. Each manual and document will be assigned to at least one individual in the CU. A list of these manuals and documents will be maintained in the UC’s office and will serve as the master list of these controlled documents.

## **4 Working Electronic Copies of CU Level 2 Quality System Documents**

Working electronic copies of the documents listed below are maintained by the indicated personnel. The electronic files are to be used for the preparation of document revisions and are secured to prevent unauthorized editing.

### **4.1 SOPs**

Electronic files are maintained by the appropriate Technical Leader (TL) and the UC.

### **4.2 IOSS Protocols and IOSS-Specific *CU Training Manual* Documents**

Electronic files are maintained by the Instrument Manager and the UC.

### **4.3 *CU Quality Assurance and Operations Manual* Documents**

Electronic files are maintained by the CU Quality Assurance Program Manager and the UC.

### **4.4 General *CU Training Manual* Documents**

Electronic files are maintained by the CU Training Program Manager and the UC.

### **4.5 Discipline-Specific *CU Training Manual* Documents**

Electronic files are maintained by the appropriate TL and the UC.

## **5 Annual Review of CU Controlled Documents**

The below personnel will ensure an annual review of the listed documents is conducted and recorded. The annual review will be recorded in an Annual Review Memo issued to the UC by the end of each calendar year. Personnel responsible for more than one area may combine those areas into one Annual Review Memo. The Annual Review Memo will contain the following information in addition to the annual review information required by the LOM (see *FBI Laboratory Practices for Document Control*):

- Any planned revisions, along with a timeline for submission of the revised document(s)
- For any document that does not require revision, a statement indicating such

### **5.1 TLs**

Each TL will issue an Annual Review Memo for their applicable SOPs, IOSS Protocols, *CU Training Manual* documents, and Instrumentation Manuals/Externally Produced Quality documents (i.e., Level 3 quality system documents).

## **5.2 IOSS Instrument Manager**

The Instrument Manager will issue an Annual Review Memo for the IOSS Protocols, applicable *CU Training Manual* documents, and Instrumentation Manuals/Externally Produced Quality documents (i.e., Level 3 quality system documents).

## **5.3 CU Quality Assurance Program Manager**

The CU Quality Assurance Program Manager will issue an Annual Review Memo for the *CU Quality Assurance and Operations Manual Documents*.

## **5.4 CU Training Program Manager**

The CU Training Program Manager will issue an Annual Review Memo for the general *CU Training Manual Documents*.

## **6 Records**

The following records will be generated and/or permanently retained in CU as a result of these practices:

- *Document Review Form* [retained in the Forensic Analysis Support Unit (FASU)]
- *CU Electronic Instrument Manuals Under Document Control Review and Approval Document*
- Master list of controlled instrumentation manuals and externally produced quality documents
- Annual Review Memos to the UC

Rev. #	Issue Date	History
10	07/15/20	Minor edit to last sentence in section 2. Minor edits made in section 3.4 for clarity. “Unit Chief” replaced with “UC” throughout. Changed title of section 4, defined “TL” within section. Changed categorization in section 5 by personnel rather than document type, minor edits for clarity.
11	03/15/21	Removed CHEMNET as a storage location for all CU controlled documents except for IOSS Protocols. Section 4.5- changed title (removed “Category of Testing”)

### **Approval**

Redacted - Signatures on File

Fire Debris  
Technical Leader:

Date: 03/12/2021

General Chemistry  
Technical Leader:

Date: 03/12/2021

Metallurgy  
Technical Leader:

Date: 03/12/2021

Paints and Polymers  
Technical Leader:

Date: 03/12/2021

Toxicology  
Technical Leader:

Date: 03/12/2021

Chemistry Unit Chief:

Date: 03/12/2021

### **QA Approval**

Quality Manager:

Date: 03/12/2021